

Appl. No. 10/807,974
Dated: October 7, 2008
Reply to Office action of July 8, 2008

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph beginning on page 13, line 17 with the following replacement paragraph (which includes markings to show changes made):

Referring to FIGS. 7 and 8, the access device 100 of the present invention is shown with laparoscopic surgical instruments 200, 250 in place within a lumen or channel 122 of the access device 100. A large instrument 200, one having a large diameter nearly that of the inside diameter of the access ~~diameter~~ device 100 itself, substantially fills the lumen 122 and substantially deforms the first seal 140 and second seal 120 as shown in FIG. 7. A small instrument 250, one having a diameter substantially less than the inside diameter of the access device 100 itself, slightly deforms the first seal 140 and the second seal 120 as shown in FIG. 8.

Please replace the paragraph beginning on page 14, line 3 with the following replacement paragraph (which includes markings to show changes made):

Referring now to FIGS. 9 and 10, one appreciates the distal end 102 of the access device 100 as comprising a second seal 120 having a check valve or zero seal 420 formed as an intersection of two occlusive portions 136, 137 of a double duckbill 420. The proximal end view of FIG. 10 reveals that the ~~second~~ first seal 140 is placed proximal of the second seal 120. The ~~second~~ first seal 140 comprises a septum having

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an orifice 145 that is sized and configured to seal in conjunction with a specific range of usable instruments.

Please replace the paragraph beginning on page 18, line 15 with the following replacement paragraph (which includes markings to show changes made):

The distal, reduced diameter portion 339 of the placement device 300 resembles an hourglass. In a preferred embodiment, there is a retention feature 364 associated with the large diameter portion 363 of the distal portion 325 of the placement device 300. An elastomeric shield 360 is associated with the retention feature 364 and extends proximally from a first end 362 to a second end 365 for a distance sized and configured to cover the reduced diameter portion 339 of the placement device 300. The elastomeric shield 360 is sized and configured to fit tightly over the elongate shaft 310 of the placement device 300 for a short distance to prevent features of the second seal 120 from intercepting body wall 20 tissue as the access device 100 is urged through the body wall 20 and into the body cavity 21. The elongate, tubular body 105 and seal system 103 are placed over the placement device 300 of the invention so that the distal second seal 140 is at rest over the reduced diameter portion of the placement device. The elastomeric shield is stretched over the distal end 120 of the elongate, tubular body 105. The elastomeric shield 360 thus forms a smooth transition between the various components of the invention. Once proper placement of the access device

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100 is confirmed, the placement device 300 may be withdrawn from the elongate, tubular body 105. The elastomeric sleeve 360 everts and follows the placement device 300 as it is withdrawn from the tubular body 105.

Please replace the paragraph beginning on page 20, line 1 with the following replacement paragraph (which includes markings to show changes made):

With reference to FIG. 27, a method for molding the elastomeric cannula 105 and seal system 103 of the present invention is shown comprising a cavity 420 and a core 440. The core 440 may comprise one or more mating portions 440a, 440b that allow the first seal 140 and the second seal 120 to be integrally formed with the elongate, tubular body or cannula 105. The first core portion 440a forms the internal lumen 422 of the tubular body 105 and the distally facing surface 470 of the first seal or septum 140. A portion 430 of the first core ~~441~~ 440a extends through the first seal or septum 140 and forms the orifice 145 there-through. A second portion ~~460~~ 440b of the core 440 is removably attached to the extending portion 430 and forms the internal cavity 462 within the double duckbill seal or check valve 120. After an elastomeric material has flowed into the cavity 420 and around the first and second cores 440a, 440b, the first and second cores are disconnected so that the first core portion 440a may be removed proximally and the second core portion 440b may be removed distally through the intersecting slits in the distal end ribs of the double duckbill seal 120. In an alternate embodiment, the entire core 440 may comprise a one-piece construction that

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is removable proximally or distally from the elastomeric tubular body 105.

Please replace the paragraph beginning on page 21, line 21 with the following replacement paragraph (which includes markings to show changes made):

When the placement device is within the cannula 105 and seal system 103 of the invention, the proximal handle 375 is moved proximally to a first position 391 (FIG. 30A) where the internal shaft 310 locates the distal shield 380 to a first, proximal position 382. The first, proximal position 382 of the shield 380 covers the distal end 102 of the cannula 105 and seal system 103 of the invention. Once complete penetration of a body wall is confirmed, a spacer 390 may be removed that maintains a preferred storage relationship between the access device 100 and the placement device 300, then the proximal handle 375 may be urged forward to second position 391a (FIG. 30B) so that the internal shaft 310 moves the distal tapered, cone-shaped member 325 and the associated shield 380 forward to expose the distal end 120 of the cannula 105 and seal system 103. The placement device 300 is then moved through a third position 391b (FIG. 30C) as it is withdrawn from the cannula 105 and seal system 103.